## REMARKS

Entry of the foregoing and examination of the above-identified application is respectfully requested.

Claims 27-30, 34-36, 41-43, 48-50 and 52-59 have been cancelled without prejudice or disclaimer of the subject matter set forth therein. These claims have been deleted and the pending claims amended to expedite prosecution and allowance of the instant application. Applicants reserve the right to pursue the subject matter of the cancelled claims in a continuation application.

Applicants note with appreciation the indication that claim 21 is allowable and claims 22-24 are rejected only under §112(2).

Claims 6, 9, 27-30, 45-50 and 54-59 have been objected to due to minor informalities. The requested corrections have been made to the claims. Withdrawal of this objection is thus respectfully requested and believed to be in order.

Claims 6, 8, 12, 27-30, 34-36, 40-44, 47-50, 52, 53 and 55-59 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly not being described in the application. This rejection is respectfully traversed and is believed to be rendered moot in part by the instant amendment.

The claims have been amended to more clearly define the DNAs encompassed by the claims. However, applicants respectfully submit that the claims previously of record were sufficiently described in the application in accordance with §112(1).

According to the Official Action, the claims recite DNA which hybridizes with DNA that codes for the claimed protease or domain under stringent conditions. The Official Action asserts that there is no description of the design or preparation of hybridizable DNAs nor evidence of the identification of such hybridizable DNAs. It is respectfully submitted that one skilled in the art would know how to design and prepare hybridizable DNA based upon the description of the specific DNA in the application, together with knowledge in the art regarding DNA preparation and hybridization principles. The application clearly defines stringent hybridization conditions and the DNA with which it hybridizes. For example, in Example 3 of the application, a human cDNA encoding a human serine protease was cloned using a mouse cDNA fragment as a probe, *i.e.*, the DNA of SEQ ID NO:3. The application further identifies various domains, such as the serine protease domain, kringle domain and scavenger domain, which one skilled in the art would recognize as being useful as primers or probes for identifying additional DNAs which fall within the scope of the instant claims. The application thus describes how to find cDNA within the scope of the invention using hybridization techniques.

That description clearly describes the claimed invention to a person skilled in the art, and shows that applicants were in possession of the invention. The original DNA sequence, that it encodes a peptide having serine protease activity, and the hybridization conditions are a "functional" description, which can be "coupled with a known or disclosed correlation between function and structure," and is sufficient to satisfy §112(1).

*See, Enzo Biochem, Inc. v. Gen-Probe Incorporated,* 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

This rejection is also overcome in view of the fact that the claims have been amended as helpfully suggested by the Examiner. The claims have been amended to more clearly define the DNAs encompassed by the claims. For example, claim 8 has been amended to recite "host cells." In addition, as stated *supra*, some claims which were rejected have been deleted. However, applicants respectfully submit that the claims previously of record were sufficiently described in the application in accordance with §112.

The Official Action further asserts at page 5 that the specification does not describe hybridizable DNAs, nor predict the conditions necessary to measure inhibitory or activating activity of substances contacted with kringle domains or scavenger receptor cysteine-rich domains. As stated *supra*, the specification clearly describes to one skilled in the art the necessary information. For example, at pages 10-11, the application states that "typical hybridization methods are well known among persons with ordinary skill in the art ..., and measurement of activity is also well known among persons with ordinary skill in the art." Information known in the art need not be repeated in the specification. The necessary information is thus described in the application as filed.

In view of the above, withdrawal of the rejection of record is respectfully requested and believed to be in order.

Claims 6, 12, 27-30, 34-36, 40-44, 47-50, 52, 53 and 55-59 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly not being enabled by the specification

for the full scope of the claims. This rejection is respectfully traversed, as it applies to the claims now of record.

The Official Action acknowledges that the specification does enable preparation of the particular sequences of SEQ ID NO: 6, but allegedly does not enable DNAs which are hybridizable. The specification describes and enabled one skilled in the art to obtain hybridizable DNA sequences.

Claim 6 recites isolated DNA which encodes a peptide having serine protease activity and which is hybridizable with DNA having a nucleotide sequence of SEQ ID NO: 3. In the specification, such DNA is specifically described. In Example 1, for example, a mouse cDNA encoding a mouse serine protease was cloned. This cDNA has the nucleotide sequence of SEQ ID NO:3, which encodes the amino acid sequence of SEQ ID NO:4. In Example 3, a mouse cDNA fragment of SEQ ID NO:3 was used as a probe to obtain a human cDNA encoding a human serine protease.

Further, Example 4 of the specification describes how to measure enzyme activity of serine proteases. Such an assay could be used to determine whether the hybridized DNA falls within the scope of the claim.

Thus, the isolated DNA of claim 6 is both described and enabled by the instant specification. Using the nucleotide sequence of SEQ ID NO:3, one skilled in the art would be enabled to obtain a cDNA of human origin encoding a human serine protease having an amino acid sequence similar to, or substantially the same as, that of SEQ ID NO:6. The application further identifies various domains, such as the serine protease domain, kringle

domain and scavenger domain, which one skilled in the art would recognize as being useful as primers or probes for identifying additional DNAs which fall within the scope of the instant claims. Claim 6 now of record is thus fully enabled by the specification.

In view of the above, withdrawal of the rejection of record is respectfully requested and believed to be in order.

Claims 44, and 5-9, 12, 14-16 and 22-59 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. This rejection is believed to now be moot in view of the instant amendment.

The claims have been amended in accordance with the Examiner's helpful suggestions. The phrase "or their partial peptides" has been deleted from claim 44. In claims 22-24, the claims have been amended to recite "of" and "and" as suggested. The recitation of "or domain" in the claims has also been deleted.

In claims 15, 16, 23, 24, 28-30, 44-46 and 51, the recitation of "domain" has been clarified, as requested by the Examiner.

In view of the above, withdrawal of this rejection is respectfully requested and believed to be in order.

Further and favorable action in the form of a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at 650-622-2360 so that prosecution would be expedited.

Respectfully submitted,

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**Attachment to Reply and Amendment dated March 6, 2003**

**Marked-up Claims 5, 6, 8, 9, 14-16, 22-26, 44-47 and 51**

5. (Four Times Amended) An isolated DNA which codes for the serine protease [or domain], as claimed in claim 21.

6. (Four Times Amended) An isolated DNA of human origin, which codes for a peptide having serine protease [or domain] activity, and is hybridizable with DNA having the nucleotide sequence of SEQ ID NO: 3, [that codes for the serine protease or domain, as claimed in claim 21] under stringent conditions.

8. (Amended) A host cell transformed by the expression vector as claimed in claim 7.

9. (Three Times Amended) A process for preparing a serine protease [or domain] comprising culturing a host cell as claimed in claim 8, and recovering the serine protease [or domain].

14. (Three Times Amended) An isolated DNA which codes for the serine protease [or] domain as claimed in claim 22.

**Attachment to Reply and Amendment dated March 6, 2003**

**Marked-up Claims 5, 6, 8, 9, 14-16, 22-26, 44-47 and 51**

15. (Three Times Amended) An isolated DNA which codes for [the] a kringle domain of a serine protease, [or domain] as claimed in claim 23.

16. (Three Times Amended) An isolated DNA which codes for [the] a scavenger receptor cysteine-rich domain of a serine protease, [or domain] as claimed in claim 24.

22. (Twice Amended) A serine protease domain consisting of an amino acid sequence from amino acid No. 578 to 822 [indicated in] of SEQ ID NO: 6.

23. (Twice Amended) A kringle domain consisting of an amino acid sequence from amino acid No. 40 to 112 [indicated in] of SEQ ID NO: 6.

24. (Twice Amended) A scavenger receptor cysteine-rich (SRCR) domain consisting of an amino acid sequence selected from the group consisting of: the amino acid sequence from amino acid No. 117 to 217, from amino acid No. 227 to 327, from amino acid No. 334 to 433, [or] and from amino acid No. 447 to 547 [indicated in] of SEQ ID NO: 6.

**Attachment to Reply and Amendment dated March 6, 2003**

**Marked-up Claims 5, 6, 8, 9, 14-16, 22-26, 44-47 and 51**

25. (Twice Amended) A process for screening physiologically active substances comprising the steps of measuring the inhibitory or activating activity of [the substances] a substance using the serine protease as claimed in claim 21, or measuring the binding affinity of [the substances] a substance to the serine protease [or domain] as claimed in claim 21.

26. (Twice Amended) A process for [screening physiologically active substances] detecting a substance capable of inhibiting or activating the serine protease as claimed in claim 21 comprising contacting a substance with the serine protease, and [the steps of] measuring [inhibitory or activating] the activity of the [substance using the] serine protease [as claimed in claim 21, or measuring binding affinity of the substance to the serine protease as claimed in claim 21, that is prepared by using a DNA which codes for the serine protease or domain as claimed in claim 21].

44. (Twice Amended) A process for preparing a serine protease domain consisting of an amino acid sequence from amino acid No. 578 to 822 of SEQ ID NO: 6 comprising culturing a host cell as claimed in claim 37, and recovering said domain [or their partial peptides].

**Attachment to Reply and Amendment dated March 6, 2003**

**Marked-up Claims 5, 6, 8, 9, 14-16, 22-26, 44-47 and 51**

45. (Twice Amended) A process for preparing a kringle domain consisting of an amino acid sequence from amino acid No. 40 to 112 of SEQ ID NO: 6 comprising culturing a host cell as claimed in claim 38, and recovering said domain.

46. (Twice Amended) A process for preparing a scavenger receptor cysteine-rich domain of a serine protease comprising culturing a host cell as claimed in claim 39, and recovering said domain.

47. (Twice Amended) A process for preparing a serine protease comprising culturing a host cell as claimed in claim 40, and recovering the serine protease.

51. (Twice Amended) A process for screening physiologically active substances comprising the steps of measuring the inhibitory or activating activity of [the] a substance using the serine protease domain as claimed in claim 22, or measuring the binding affinity of [the] a substance to the serine protease domain as claimed in claim 22.